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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,792	02/24/2004	Robert G. Turcott	A04P3001-US1	3760
24473	7590	09/19/2006	EXAMINER	
STEVEN M MITCHELL PACESETTER INC 701 EAST EVELYN AVENUE SUNNYVALE, CA 94086			HOLMES, REX R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/786,792	TURCOTT, ROBERT G.	
	Examiner	Art Unit	
	Rex Holmes	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 27-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/24/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group 1, Claims 1-26 in the reply filed on 09/01/06 is acknowledged.
2. Claims 27-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/01/06.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-9 and 14-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Sun et al. (U.S. Pat. 7,079,897 hereinafter "Sun").
5. Regarding claims 1-9 and 14-22, Sun discloses a rate responsive pacemaker with multiple sensors that monitor different hemodynamic responses (Col. 4, ll. 58-64) for different heart rates and then the data is registered and stored (Col. 6, ll. 65-67 & Col. 7, ll. 1-7). The stored maximum exertion levels may then be used to update a long-term maximal exertion level, and the slope of the rate-response curve is adjusted to map the updated long-term maximal exertion level to a maximum allowable pacing

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rate. The stored maximum exertion levels may also be used to update a sensor target rate which is used to adjust the slope of the rate response curve (abstract). It is further disclosed that the relative pacing threshold is measured and averaged over a specified period, that period being anywhere from 30 seconds to 5 minutes. (Col. 5, ll. 49-64; Col. 7, ll. 30-35). It is also disclosed that the sensed target rate can be updated daily (Col. 6, ll. 3-9).

6. Sun further discloses that the pacemaker contains a storage device (Col. 4, ll. 39-40) that saves sensed information, and uses that information alone or in combination with the current sensed information to determine the pacing preferences (Col. 7, ll. 55-67). Sun further discloses that a plurality of measures of hemodynamic response are stored for each interval (Col. 6, ll. 65-67 & Col. 7, ll. 1-7). Sun also discloses that the pacemaker contains a hemodynamic pulse pressure sensor that utilizes an accelerometer to adjust the rate at which the pacemaker paces the heart in the absence of a faster intrinsic rhythm (Col. 4, ll. 58-61).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-9 and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun (U.S. Pat. 6,408,208 hereinafter "Sun' ") in further in view of Bennett et al. (U.S. Pat. 5,154,170 hereinafter "Bennett").

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9. Sun' discloses a rate responsive pacemaker with multiple sensors that monitor different hemodynamic responses (Col. 3, ll. 31-51) for different heart rates and then each sensor provides for corresponding pacing intervals (Col. 3, ll. 40-45). Sun' further discloses that the pacemaker contains a storage device (Fig. 2, 230) that saves sensed information, and uses that information alone or in combination with the current sensed information to determine the pacing preferences (Col. 6, ll. 58-67 and Col. 10, ll. 9-22). Sun' further discloses that a plurality of measures of hemodynamic response are stored for each interval (Col. 9, ll. 51-67).

10. Bennett discloses a rate responsive pacemaker that monitors the patients heart rate utilizing two sensors, an activity sensor, and a pressure sensor (Col. 10, Lines 11-40). Bennett also describes that ten rate response functions are established for each sensor, such that each function provides for excursion between selected lower and upper pacing rates within the available range of sensor outputs corresponding therewith (Col. 13, Lines 3-24). Bennett further discloses that based on the functions the pacemaker generates pacemaker rates (Col. 14, ll. 3-8).

11. Regarding claim 1-9 and 14-22, Sun' discloses the claimed invention except for the measuring of a plurality of different pacing intervals and the determination of new pacing intervals based on the pacing intervals. Bennett teaches that it is known to use the derived pacing rates along with sensed intervals as set forth in Col. 13, Lines 3-24 to provide an output means for providing optimized pacing rates. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rate responsive pacemaker as taught by Sun', with the optimized pacing rate

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as taught by Bennett, since such a modification would provide the rate responsive pacemaker with a optimized pacing rate based on a patients physiological condition for providing enhanced pacing during times of increased activity.

12. Claims 10-13 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Sun' and Bennett or Sun as applied to claims 1 and 14 above, and further in view of Carlson (U.S. Pat. 6,366,811).

13. Sun' and Bennett; and Sun discloses a motion sensitive pacemaker as described in detail above, and further discloses that it utilizes an accelerometer and hemodynamic data to determine motion (Sun, Col. 6, ll. 32-38). However, neither Sun' and Bennett or Sun specifically disclose that when significant motion is present that it either stops pacing and/or storing information that correlates to the pacing. Carlson discloses a pacemaker with a hemodynamic pulse pressure sensor that utilizes an accelerometer and threshold values to determine motion so that measurements can be taken during relative steady states of hemodynamic conditions to minimize motion artifacts (Carlson, Col. 3, ll. 4-12 & Col. 7, ll. 17-21). Regarding claims 10-13 and 23-26, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inventions of Sun' and Bennett or Sun with the motion sensing techniques of Carlson in order to minimize motion artifacts in the signal.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes



George Evanisko

Primary Examiner

9/15/06